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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,693	07/03/2001	Lewis T. Williams	PP01521.101	7839

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,693	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-40 are pending in the present application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group Restriction:

Group I, claims 1-16, 36-37 and 39, drawn to a method for producing at least one vector encoding an array of antigens for expression in an antigen-presenting cell, a composition comprising at least one vector produced by the same method, and methods for activating T cells *in vivo*, for killing a target cell *in vivo*, and for treating cancer using the same composition.

Group II, claims 1-16, 36-37, 38 and 40, drawn to a method for producing at least one vector encoding an array of antigens for expression in an antigen-presenting cell, a composition comprising at least one vector produced by the same method, and methods for activating T cells *in vivo*, for killing a target cell *in vivo*, and for preventing infection or treating an infection using the same composition.

Group III, claims 17-29, 32-35, 37 and 39, drawn to a method for producing an antigen-presenting cell that presents an array of antigens, an antigen presenting cell produced by the same method, and methods for activating T cells, for killing a target cell *in vivo*, and for treating cancer using the same antigen presenting cell.

Group IV, claims 17-29, 32-35, 37, 38 and 40, drawn to a method for producing an antigen-presenting cell that presents an array of antigens, an antigen presenting cell produced by the same method, and methods for activating T cells, for killing a target cell *in vivo*, and for preventing infection or treating an infection using the same antigen presenting cell.

Group V, claims 17-27, 30-35, drawn to a method for producing an antigen-presenting cell that presents an array of antigens, an antigen presenting cell produced by the same method, and a method for inducing a toleragenic response using the same antigen presenting cell.

The technical feature linking Groups I to V appear to be that they all relate to a vector encoding an array of antigens for expression in an antigen-presenting cell.

However, Thomson et al. (Proc. Natl. Acad. Sci. 92:5845-5849, 1995) already teach the construction of a recombinant vaccinia virus containing a DNA sequence encoding for nine minimal CD8+ CTL epitopes derived from several Epstein-Barr virus nuclear antigens for expression in target cells (antigen presenting cells) to be presented to appropriate CTL clones (see abstract and Fig. 1). Since the recombinant vector and target cells of Thomson et al. are indistinguishable from those produced by the presently claimed invention, the technical feature linking the inventions of Groups I to V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity according to Rule 13.1 PCT.

Consequently the claimed subject matter was broken up into the aforementioned Groups of Invention. The inventions are distinct, each from the other for the following reasons:

The method in each Group is materially different and plurally independent from the methods of any other Groups because each is practiced with materially different process steps, starting materials for attaining distinct desired end-results; the special steps and utilized starting materials are the special technical features which distinguish each method from the others. As such, the methods for activating T cells *in vivo*, for killing a target cell *in vivo*, and for treating cancer using at least one vector encoding an array of antigens for expression in an antigen-presenting cell in Group I; the methods for preventing infection or treating an infection using at least one vector encoding an array of antigens for expression in an antigen-presenting cell in Group II; the methods for activating T cells *in vivo*, for killing a target cell *in vivo*, and for treating cancer using an antigen-presenting cell that presents an array of antigens in Group III; the methods for preventing infection or treating an infection using an antigen-presenting cell that presents an array of antigens in Group IV; and the method for inducing a toleragenic response using an antigen presenting cell that presents an array of antigens in Group V are materially different methods which require different technical considerations, starting materials (e.g., patients having a cancer or an infection) and endpoints to achieve different goals.

Species Restriction:

Should Applicants elect Group I or Group II, claims 1-2 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named antigen-presenting cell as recited in the Markush Group of claim 2.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 1 and 8-9 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named immunostimulatory cofactor as recited in the Markush Group of claim 9.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 1 and 10-11 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named selectable marker as recited in the Markush Group of claim 11.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claim 1 is generic to a plurality of disclosed patentably distinct species of target cell comprising:

(a) cancer cell; (b) a virus; (c) a bacterium; and (d) a parasite.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect Group III or Group IV or Group V, claims 17-18 and 26 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named antigen-presenting cell as recited in the Markush Group of claim 18.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 17 and 23-24 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named selectable marker as recited in the Markush Group of claim 24.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 17 and 27 are generic to a plurality of disclosed patentably distinct species of target cell comprising:

(a) cancer cell; (b) a virus; (c) a bacterium; and (d) a parasite.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 17-27, 28, 30 and 32-35 are generic to a plurality of disclosed patentably distinct species of immunomodulatory cofactor comprising:

A specifically named immunostimulatory cofactor as recited in the Markush Group of claim 35.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER